**CONTRACT FOR THE PERFORMANCE OF THE CLINICAL TRIAL “………..”**

**PROTOCOL CODE:**

**EudraCT Nº:**

In Madrid,

# BETWEEN

On the one hand, Mr. / Mrs. \_\_\_\_\_ and Mrs. \_\_\_\_\_, respectively, acting in the name and on behalf of \_\_\_\_ (hereinafter DEVELOPER), with registered office at C/\_\_\_\_, being empowered for this act by virtue of power of attorney nº \_\_\_\_, duly registered in the Mercantile Registry of \_\_\_\_, granted before the Notary Public of the Illustrious College of \_\_\_\_ D.\_\_\_\_ on the date \_\_\_\_.

On the one hand, Mr. \_\_\_\_(name of the legal representative of the CRO), as legal representative of \_\_\_\_(name of the CRO) and with registered office at (full address of the CRO) at \_\_\_\_ (town and post code), (hereinafter CRO), acting on behalf of the PROMOTER \_\_\_\_(full name, address and VAT number of the PROMOTER entity, pharmaceutical laboratory, scientific society, legal entity), (hereinafter PROMOTER), authorized for this purpose, in accordance with the powers of attorney issued at \_\_\_\_, dated \_\_\_\_ before the Notary D. \_\_\_\_. Not exempting from the responsibility incumbent on the PROMOTER according to RD 1090/2015, of December 4, regulating clinical trials with medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Registry of Clinical Studies, (hereinafter RD 1090/2015, of December 4.

On another hand, Miss. Emma Méndez Calleja, acting on behalf of and representing the **FOUNDATION FOR BIOMEDICAL** RESEARCH OF THE UNIVERSITY **CHILDREN'S HOSPITAL JESUS CHILD** (hereinafter,the **FOUNDATION**), established in Avda. Menéndez Pelayo, no 65 (28009 Madrid),in accordance with the powers issued in Madrid, dated March 18, 2021, with protocol no. 604, before the Notary Dña. Carmen Boulet Alonso.

On another hand, Mr. Cesar Gómez Derch , also acts as Managing Director, on behalf and on behalf on the HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS (hereinafter **HOSPITAL),** with registered office at Avda. Menéndez Pelayo, 65 (28009 Madrid), with CIF NO. Q-2877003-J, by virtue and in accordance with the agreement between the FOUNDATION and the HOSPITAL

And on the other hand Dr…………………………………., acting in his own name and right (hereinafter, the **PRINCIPAL INVESTIGATOR**), with address, for the purposes of notifications, in the Service ……………………… of the HOSPITAL located in Avda. Menéndez Pelayo, 65 (28009 Madrid)*.*

Recognizing the **PARTIES** the mutual capacity necessary to be bound by this Agreement (hereinafter, the **PARTIES)**

# RECITALS

1. That the **SPONSOR**is interested in conducting the Clinical Trial described in the first clause of the Contract.
2. That ……………………. (hereinafter, **CRO**)**,** as a representative of the **SPONSOR**, may be entitled to make payments on its behalf.
3. That the **FOUNDATION,** in accordance with the provisions of its Statutes, has as its roles the development of research, innovation and knowledge management, inspired by the principle of legality, ethical principles and professional ethics of which are part of the management of Clinical Trials carried out in the HOSPITAL. Furthermore, the Foundation, in accordance with the provisions of the current Convention signed on June 17, 2009 with SERMAS, has, among other commitments, the management of Clinical Trials carried out in the **HOSPITAL.**

On the basis of the foregoing, the **PARTIES** decide to enter into this Agreement, in accordance with the following:

# CLAUSES

**FIRST. - PURPOSE**

* 1. The purpose of this Agreement is the conduction of the Clinical Trialentitled……………………………………………………………………………………………………………………………. (hereinafter, the **Trial**) with protocol code …………… (hereinafter, the **PROTOCOL**)**,** to be carried out in **HOSPITAL** units, without prejudice to the use for organizational reasons, any technique or visit may be carried out in an external unit, identified in Annex I to this contract, under the direction and responsibility of the **PRINCIPAL INVESTIGATOR** of the same. *The* ***Trial*** *will be conducted according to the content specified in the* ***PROTOCOL****, of version and date matching those contained in the updated favorable opinion of the Ethics Committee for Research with Medicinal Products (hereinafter* ***CEIm).***

# SECOND. - BEGINNING AND DURATION

* 1. This Agreement shall enter into force on the day of its signature and shall be in force until the end of the **Trial**, without prejudice to the provisions of the Ninth Clause. For this purpose, the **TRIAL** shall not be deemed terminated until the **PARTIES** have fulfilled all of their obligations under this Agreement.
  2. The  **Trial** shall not be initiated under any circumstances until the favorable opinion of the relevant **CEIm** and the required authorization of the Spanish Agency for Medicines and Healthcare Products have been issued (hereinafter, **AEMPS**) under Royal Decree 1090/2015, and any other authorization that, if any, is required by applicable law. The effectiveness of this contract is subject to the obtaining of such authorizations.
  3. The expected duration of the  **Trial** is ………… months, according to the **PROTOCOL**.

**THIRD. - APPLICABLE REGULATIONS**

3.1 Clinical Trials Regulations

* + 1. Law 10/2013 of 24 July incorporating into Spanish law Directives 2010/84/EU of the European Parliament and of the Council of December 15, 2010 on pharmacovigilance and 2011/62/EU of the European Parliament and of the Council of June 8, 2011, on the prevention of the entry of counterfeit medicines into the legal supply chain, and amended Law 29/2006 of July 26 on guarantees and rational use of medicines and medical devices. Royal Legislative Decree 01/2015, of July 24, which approves the consolidated text of the Law on Guarantees and Rational Use of Medicines and Medical Devices. Royal Decree 1090/2015 of December 4, regulating Clinical Trials with medicines, the Committees on Ethics of Drug Research and the Spanish Registry of Clinical Studies (hereinafter, **RD**1090/2015).
    2. Royal Decree 1015/2009, of June 19, regulating the availability of medicines in special situations.
    3. Decree 39/1994 of April 28 regulating the competences of the Community of Madrid in the field of Clinical Trials with medicinal products.
  1. Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (Reg General Data Protection) and Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, as well as the rest of the current regulations on the protection of personal data that could result application.
  2. Law 41/2002, of November 14, basic regulatory of the autonomy of the patient and of rights and obligations in the field of information and clinical documentation.
  3. Law 14/2007, of July 3, on Biomedical Research and Royal Decree 1716/2011, of November 18, laying down the basic requirements for the authorization and operation of biobanks for biomedical research purposes and the treatment of samples human-friendly biological bodies, and regulating the operation and organization of the National Registry of Biobanks for biomedical research, for biological samples of human origin, and the treatment of biological samples of human origin, which have been obtained as a result of the **TRIAL** directly or indirectly and especially provided that they are to be used for biomedical research purposes after the **TRIAL** is completed.
  4. Law 1/1998, of March 2, on Foundations of the Community of Madrid. In accordance with article 23, employers may contract with the Foundation, either in their own name or a third party, subject to authorization by the Protectorate of Foundations.

Law 53/1984, of December 26, on incompatibilities of staff in the service of the Public Administrations and Royal Decree 598/1985, of April 30, on incompatibilities of personnel in the service of the Administration of the State, Social Security and Entities, Agencies and Dependent Companies.

* 1. THE ICH (International Conference of Harmonization Guideline) standards for Good Clinical Practice (BPC): GCP E6 (R2).
  2. Basic ethical principles set out in internationally accepted recommendations, including the Helsinki Declaration as updated.
  3. The national and international deontological rules and anti-corruption legislation contained in the OECD Convention, adopted on November 21, 1997, also contained in the Foreign Corrupt Practices Act (FCPA), which may apply to one or all **PARTIES** to this contract.
  4. Notwithstanding the foregoing, the **PARTIES** undertake at all times to respect and comply with the law applicable to the signing of this Agreement and during its validity. If the relevant regulations are amended in the course of the contract, it shall be automatically understood to apply to that Contract, unless the relevant rule establishes a transitional regime for different application.

# FOURTH. - OBLIGATIONS OF THE PARTIES

* 1. The **PARTIES** are obliged to fully comply with obligations provided for this Agreement, in accordance with the provisions of this Agreement and in the **PROTOCOL.**
  2. In addition, **PARTIES** shall comply with these commitments:
     1. Collaborate in the follow-up visits of the **TRIAL** carried out by: (1) the **CEIm**, (2) the monitors and auditors acting at the request of the **SPONSOR** and (3) the competent authorities, when they carry out inspection proceedings. These visits, except inspection visits, will be communicated at least one week in advance, unless there is agreement of another period between the **PARTIES.** During the conduct of such monitoring, monitoring and auditing visits, technical or organizational measures shall be taken to ensure maximum compliance with the regulations on the protection of personal data.

The **PRINCIPAL** **INVESTIGATOR**, the **SPONSOR,** the monitors and auditors shall comply with the internal rules of the **HOSPITAL** and the **FOUNDATION,** which will be provided by these entities, as well as the indications on the development of the **TRIAL** by the **CEIm** responsible for its follow-up.

* + 1. The **PARTIES** will not agree between them or with third parties outside this document, with respect to the performance of the **TRIAL**, agreements or terms outside this that hinder, nuance, exception, contravene or prevent the compliance with the respective obligations assumed or involving the assumption of others contrary to the applicable legislation. For this purpose, each **PARTY** states that as of the date of this Agreement they are not party to any agreement or covenant that contemplates any of the agreements or terms referred to above. In particular, under this Clause, the **PARTIES** agree that no consideration of any kind other than those provided for in this Agreement may be agreed or paid for. Excluded from this prohibition are expenses for meetings held for the purpose of organising and supervising the conduct of the **TRIAL**, as well as for analyzing or publicizing the results of the **Trial** (presentations or scientific publications).
  1. **SPONSOR** is obliged, in addition to those provided for in the applicable regulations, to provide continued support to the **PRINCIPAL INVESTIGATOR** and to provide the latter and the **CEIm** with any new relevant information raise the drug under investigation.
  2. It is the obligation of the **FOUNDATION** to manage this **TRIAL**, receiving these payments made on behalf of the **SPONSOR/CRO** and distributing them in accordance with annex I.
  3. The **PRINCIPAL INVESTIGATOR** undertakes to keep the identification codes of the subjects included. The **SPONSOR,** the **PRINCIPAL INVESTIGATOR** and the **HOSPITAL, depending on their responsibilities,** undertake to keep the essential documents of the **TRIAL** for the time and under the conditions established in the current legislation.

The **PRINCIPAL INVESTIGATOR** is also responsible for the selection of the members of the research team and the support staff to the **TRIAL**, which may consist of both natural persons and commercial entities or other nature, which have appropriate material and human means for the execution of the same. Annex II detailing the list of members of the research team at the time of signing this contract is attached. Any variation in the research team must be communicated to the **CEIm** in accordance with current regulations.

# FIFTH. - ECONOMIC ASPECTS

* 1. The amount of this **TRIAL** has initially been budgeted in ………………………………………………………………………………………………………………….) per patient, VAT not included (hereinafter, **TRIAL Budget**), as set out in the Economic Report of the **TRIAL** (Annex I), which specifies all the economic aspects of it.

Such amount does not include in any case a HOSPITAL, FOUNDATIONand/or PRINCIPAL INVESTIGATORobligation to recommend, prescribe, purchase, use or arrange the use of any product of the SPONSOR**.**

In addition, at the signing of this contract the **SPONSOR** will pay the amount of **TWO THOUSAND ONE HUNDRED AND TWENTY-TWO EURO** (€2.122,00), in single payment, non-refundable, as administrative and contractual management expenses.

The PROMOTER will additionally pay to the FOUNDATION 10/15 % of the TRIAL budget to cover the Pharmacy Service expenses. (The % depends on the complexity of the preparation or dispensing of the drug

* 1. The amount to be paid by **SPONSOR** /**CRO** during the execution of the **TRIAL** shall be determined by application of Annex I and shall be paid to the **FOUNDATION** in the payments detailed below:
     1. The BUDGET of the **TRIAL** shall be paid at least on a six-monthly basis as detailed in the table of amounts per visit and the recruited subject listed in Annex I, until full payment of the amount constituted by that budget. For these purposes, the **CRO** and the **PRINCIPAL INVESTIGATOR** shall keep the **FOUNDATION** informed on a six-monthly period.
     2. These payments are considered credit memos, dependent on the settlement of the final amount of the **TRIAL.**
  2. The final amount to be paid by the **SPONSOR/CRO** for the execution of the **TRIAL** shall be determined by reason of the activity actually carried out for the execution of the **TRIAL** (hereinafter, **Definitive Amount**). The Definitive Amount shall be calculated as follows:

Within a maximum period of (3) three months, from the end of the **TRIAL** at the **HOSPITAL**, the **CRO** and the **PRINCIPAL INVESTIGATOR** shall communicate in writing to the **FOUNDATION** the total number of: (1) subjects recruited and evaluated, (2) visits actually made, (3) incidents produced, as well as (4) of any TRIALs, analyses, exploration, consultation or hospital stay of an extraordinary nature, reflected or not reflected in the Economic Report (Annex I).

* + 1. As soon as possible, since the communication of the information referred to in the previous point has taken place, the **FOUNDATION** shall calculate, issue and notify to the **CRO** by final invoicing of the **Trial**, the liquidation of the final amount, as well as, where appropriate, shall claim the outstanding amounts, which must be paid within one (1) month, without further formal notice. The final payment shall mean that the economic obligations on the part of the SPONSOR are terminated.
  1. All payments must be made against presentation of an invoice, to which VAT will be applied in accordance with the applicable regulations on the date of issuance of the same and on behalf of the **SPONSOR** or ECONOMIC RESPONSIBLE established (i.e. legalized and **SPONSOR** in Spain).

Invoices will be issued to THE CRO \_\_\_\_\_\_\_\_with the following billing details:

|  |  |
| --- | --- |
| Name: |  |
| Job title: |  |
| Address: |  |
| Tel. No. (in event of queries): |  |
| mail: |  |
| VAT No. (to be inserted if outside the UK): |  |

Invoices issued to the **CRO** shall be paid by the next payer, whose details shall be:

Invoices will be sent for management to the following address:

* 1. Payments to the FOUNDATION shall be made by bank transfer, with the costs to be borne by the PROMOTER / CRO, to:

Holder: FOUNDATION FOR BIOMEDICAL RESEARCH OF THE UNIVERSITY CHILDREN’S HOSPITAL JESUS CHILD.

Banking Entity: CAIXABANK

No Count : 2100 2624 4113 0003 6269

IBAN: ES21 2100 2624 4113 0003 6269

SWIFT: CAIXES BB XXX

CIF: G85289924

* 1. The payments made by the **SPONSOR /CRO** to the **FOUNDATION** will be fully liberating for the first, being the responsibility of the **FOUNDATION** the payment of the amounts that, if applicable, correspond to the investigators of the **TRIAL**.
  2. The **PARTIES** agree that, if the **HOSPITAL** lacks the equipment necessary to properly perform the TRIAL, the **SPONSOR** will provide it to the **HOSPITAL** free of charge ceding its use, directly or through a third party. In addition, the **SPONSOR** will bear the cost and will be responsible for the supply, installation, maintenance, calibration and removal of the equipment, and the training of the personnel for its handling, if necessary. In no case shall the HOSPITAL, the **FOUNDATION,** nor the PRINCIPAL **INVESTIGATOR** be responsible for its maintenance, nor for its possible loss. **N/A**

The sponsor shall have no liability for damages of any kind, including personal injury or property damage, resulting from the use of the equipment, except to the extent that such damages were caused by negligence or misconduct of the sponsor.

The Equipment will always be the property of the **SPONSOR** or a third party and shall bear the corresponding identification in this regard. The Equipment should only be used to perform the TRIAL, and at the end of the TRIAL will be returned to the **SPONSOR** or a third party at no cost to the **HOSPITAL** or **FOUNDATION.**

When you receive a return request, the **PRINCIPAL INVESTIGATOR** will make the Equipment available to the **SPONSOR** or the third party designated by the PROMOTER for collection.

At the end of the **TRIAL,** the **SPONSOR** may assign the Equipment to the **HOSPITAL** or the **FOUNDATION** free of charge, for which the necessary documents will be formalized.

# In the event that additional equipment needs are detected during the performance of the TRIAL and after the signing of this contract, the PARTIES must sign an addendum that collects the equipment made available in compliance with the terms and conditions set out in the preceding paragraphs.

# SIXTH.-INSURANCE AND LIABILITIES

The **SPONSOR** has a liability insurance policy underwritten that complies in all its aspects with the provisions of RD **1090/2015.** This policy, no ………………………has been agreed with the insurer ………………………………………………………………. and is in force as the **SPONSOR** is aware of the payment of premiums. This policy also includes in its scope of coverage, and so explains, the **PRINCIPAL INVESTIGATOR**, its collaborators and the **HOSPITAL** and the **FUNDATION** (copy of the policy or certificate is attached of it).

# SEVENTH. - CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA.

* 1. Confidentiality. The **PARTIES** undertake to make all means at their disposal to ensure the confidentiality of the information provided for the performance of the **TRIAL** and obtained during its completion, as well as that of data of a nature personnel of the subjects recruited for it, in order to comply with all the requirements established in the current regulations. Information that: (i) is in the public domain, (ii) was previously known to the **PARTIES** at the time of disclosure, or (iii) is required to disclose by law shall be exempt from this commitment to confidentiality.
  2. DATA PROTECTION. All **PARTIES,** to the extent that they process personal data of the subjects of the **TRIAL**, shall take appropriate measures to protect them and prevent access to them by unauthorized third parties. THE **PARTIES** are required to comply with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 and Organic Law 3/2018 of December 5 on the Protection of Personal Data and guarantee of digital rights. Likewise, such legislation will apply to the personal data contained in this contract. If necessary, the **PARTIES** shall formalize the agreements necessary to ensure compliance with these legal obligations.
  3. THE **HOSPITAL,** the **PRINCIPAL INVESTIGATOR** and the **FOUNDATION** will adequately process the personal data of the subjects participating in the **TRIAL** in such a way that they cannot be identified by the **SPONSOR** and **CRO**. They will only access personal data of the subjects of the **TRIAL**, in which they are identified, to the extent permitted by informed consent and in the exercise of their professional functions, monitors and/or representatives designated by the **SPONSOR** and **CRO**, auditors and competent authorities.

The PARTIES to this contract undertake the following mutual agreement:

* + - Access to personal data only when it is essential for the good development of the project
* Treat the data for the sole purpose of complying with the subject matter of the contract
  + If either party considers that another infringes the GDPR, the LOPDGDD, or any other data protection provision of the Union or the Member States, it shall immediately inform the others in order to proceed with its prompt remedy.
  + Assume the corresponding responsibility in case the data is assigned, another purpose other than the fulfilment of the object of this contract, communicate or use them in breach of the stipulations of the current regulations, responding for the violations that he would have personally incurred.
  + Do not allow access to personal data to any employee of their responsibility who does not have the need to know them for the provision of the services.
  + Not disclose, transfer, assign or otherwise communicate personal data, whether verbally or in writing, by electronic means, paper or by computer access, or even for storage, to any third party, unless there is authorization or prior instruction for this purpose.
  + It shall keep a record of all categories of processing activities carried out pursuant to this contract, containing the information required by the Article 30.2 GDPR and 31 LOPDGDD.
  + Ensure the necessary training in the protection of personal data of persons authorized to process personal data.
  + Support each other in carrying out data protection impact assessments, where appropriate. Support each other in carrying out prior consultations with the Supervisory Authority, where appropriate.
  + Make available to the other party all the information necessary to demonstrate compliance with its obligations, as well as for the conduct of the audits or inspections carried out by the other party in order to verify the correct compliance of the contract.
  + Adopt and apply the security measures stipulated in this contract, in accordance with Article 32 of the GDPR, which guarantees the security of personal data and prevents its alteration, loss, treatment or unauthorized access, having account of the state of technology, the nature of the data stored and the risks to which it is exposed, whether they come from human action or from the physical or natural environment.
  + Designate a data protection officer and communicate its identity and contact details to the other party, as well as comply with all provisions of Articles 37, 38 and 39 of the GDPR, and 35 to 37 of the LOPDGDD.
* In the event that either party is required to transfer or allow access to personal data liable of the other to a third party under EU or Member State law applicable to it, it shall inform the other of that legal requirement in advance, unless prohibited for reasons of public interest.
* In the event that the processing includes the collection of personal data, the procedures for the collection of the data will be established, in particular with regard to the reliable identification of users, the duty of information and, where appropriate, the obtaining the consent of those affected, ensuring that these instructions comply with all legal and regulatory requirements required by current data protection regulations.
  + Supervise the processing and compliance with data protection regulations by the other party.
  1. SAFETY MEASURES AND SAFETY VIOLATIONS Taking into account the state of the art, the costs of implementation, and the nature, scope, context and purposes of the processing, as well as risks of variable probability and severity for rights and the freedoms of natural persons, the parties shall apply appropriate technical and organisational measures to ensure a level of security appropriate to the risk, including, where appropriate, inter alia:
     1. pseudonymization and encryption of personal data;
     2. the ability to ensure the permanent confidentiality, integrity, availability and resilience of processing systems and services, as well as the availability and access to personal data quickly in the event of a physical or technical incident.
     3. a regular verification, evaluation and assessment of the effectiveness of technical and organizational measures to ensure the safety of the processing.
     4. a catalogue of security measures recognized in information security regulations or standards.

In assessing the adequacy of the level of security, the parties shall take into account the risks presented by the processing of data, in particular as a result of the accidental or unlawful destruction, loss or alteration of personal data transmitted, stored or treated otherwise, or unauthorized communication or access to such data. The parties shall allow and contribute to the conduct of audits, including inspections, to the other party.

In addition, in case of modification of the current regulations on data protection or other related regulations that are applicable to the processing subject to this contract, the parties guarantee the implementation and maintenance of any other security measures that may be required of it, without changing the terms of this contract.

In the event of a breach of the security of personal data in the information systems used by the parties for the provision of the Services, they shall notify each other, without undue delay, and in any case before the maximum period of 24 working hours, the breaches of the security of personal data held by them that they are aware of, together with all information relevant to the documentation and the communication of the incident in accordance with the provisions of Article 33.3 of the GDPR.

In such case, each party to the extent applicable shall communicate data security violations to the Data Protection Authority and/or interested parties in accordance with the provisions of the current regulations.

* 1. INFORMATION RIGHT. Each of the PARTIES is informed that the professional contact details will be processed by the other party for the purpose of managing this Contract, being the basis of the processing being the execution of the same. The data will be kept for the duration of the contractual relationship and until they prescribe any responsibilities arising from it. Besides, the PARTIES will not transfer the data to third parties, except by legal obligation. In addition, the PARTIES may exercise at any time their right of access, rectification, limitation, deletion, opposition and portability, with respect to their personal data, by contacting the data protection delegates of the PARTIES:

By theFoundation:[delegatedatos.fibhnjs.salud.madrid.org](mailto:delegadodatos.fibhnjs@salud.madrid.org)

By the Hospital: pdatos.hnjs@salud.madrid.org

By the Principal Investigator:

By the Promoter:

THE PARTIES may also file a complaint with the Spanish Data Protection Agency.

If either PARTY wishes to make a transfer of Personal Data from signatories outside the European Economic Area (EEA) or Switzerland, it shall be made only where permitted by applicable law in the EEA, on the basis of the legal transfer mechanisms and with the authorization of the rest of the PARTIES concerned.

# EIGHTH. - INVESTIGATIONAL DRUGS

* 1. The **SPONSOR** shall provide free research drugs, including comparison drugs and placebos, in the terms set out in DR **1090/2015.**
  2. The investigational drug will be supplied through the **HOSPITAL** Pharmacy Service, being dispensed in a controlled manner and in accordance with the **protocol** guidelines.

The investigational medicinal product will not be made available to the **HOSPITAL** or the **PRINCIPAL INVESTIGATOR** until the favorable report of the **CEIm** and the required authorization of the **AEMPS** are available.

**NINETH. - MODIFICATION, CANCELLATION OR SUSPENSION AND CONTRACT** **RESOLUTION.**

**Modification**

* 1. Any modification to the provisions of this Agreement shall be made in writing and signed by the **PARTIES** as *an addendum* thereto. In any event, the amendment shall observe the provisions of Article 26 of **DR 1090/2015**.

# CANCELLATION OR SUSPENSION

* 1. The **TRIAL** may be cancelled or suspended by one of the **PARTIES** in any of the situations provided for in Article 27 of DR **1090/2015,**as well as in the following cases:
     1. For non-compliance with the essential obligations assumed by one of the **PARTIES**.
     2. For non-compliance or defective performance of the remaining obligations assumed by the other **PARTY,** provided that such non-compliance is not remedied within fifteen (15) days from the time the other Party instills compliance in writing.
     3. By mutual agreement between the PARTIES, expressed in writing.

# CONTRACT TERMINATION

* 1. Termination or suspension of execution of the **TRIAL** shall allow the termination of the Contract by the Party that has not breached its contractual obligations.
  2. The PARTIES will guarantee the safety of the subject at the end of the TRIAL, as well as the continuity of the treatment, and will therefore continue to provide the trial treatment to the subjects in compliance with the provisions of Royal Decree 1015/2009, of June 19, which regulates the availability of drugs in special situations. Should there be a request by CEIm for continuation of treatment, the parties will agree on the supply taking into account the feasibility of production and the efficacy and safety data of the investigational drug/trial treatment

# TENTH. - RESULTS AND PUBLICATIONS

* 1. All the data, the results of the **TRIAL**, as well as all the works and intellectual and industrial property rights derived therefrom, are the property of the **SPONSOR**, being the **PARTIES** subject to the provisions of the applicable legislation.

This circumstance will not prevent the **PRINCIPAL INVESTIGATOR** and the **FOUNDATION** from using the results in their professional non-commercial research and teaching activities, safeguarding SPONSOR’s industrial and intellectual property rights of the **SPONSOR** and in compliance with the provisions of the **PROTOCOL**.

* 1. In accordance with the provisions of **RD 1090/2015**, the **SPONSOR** undertakes to publish, once the **TRIAL** has been completed, the results obtained, whether positive or negative. This publication will take place in publicly available scientific media, preferably in scientific journals.
  2. If the final results of the **TRIAL** are not published by the SPONSOR, the **PRINCIPAL INVESTIGATOR** may disclose, for professional purposes and in scientific journals and publications, such data, discoveries or inventions, with at least mention of the **SPONSOR** according to the following criteria: Trials with not marketed products: in the first year after its authorization and marketing in any country; Trials s conducted after marketing: in the year after the end of the TRIAL, unless publication is committed in a peer review medical journal or contravenes national legislation. THE **SPONSOR**, must receive for review, a copy of the proposed text for publication and/or disclosure, in accordance with the provisions of the **PROTOCOL** and, if nothing is indicated in this regard, at least forty-five (45) days before the date of submission to the scientific journal and at least twenty (20) days before, in the case of a summary. In any case, the **PRINCIPAL INVESTIGATOR** may only use this data with the express written permission of the **SPONSOR.**
  3. The **PARTIES** agree that the compensation provided (i) constitutes fair compensation in relation to the services provided in their experience; (ii) that does not constitute an incentive for, or in exchange for, past, present or future prescriptions, purchases, recommendations, use, obtaining a preferential form status or dispensing of any product from the **SPONSOR** or in a manner any contingent or any similar activity; And, (iii) does not imply an alteration of the judgment of the **PRINCIPAL INVESTIGATOR** and HOSPITAL in relation to the advice and care of each of the Subjects.

# ELEVENTH ANTIBRIBERY CLAUSE

* 1. The anti-corruption policy provides that all employees of the **PARTIES** and any third party acting for them or on their behalf have no interest or commitment that conflicts or prevents them from carrying out their obligations hereunder Contract. All activities must be carried out in strict compliance with and in compliance with ethical standards and applicable law. The **PARTIES** consider complete and transparent behaviour to be essential by pursuing a zero-tolerance policy with any corrupt practice.
  2. Employees of the **PARTIES** and any third party acting on their behalf shall not make payments of any kind, under any circumstances, directly or indirectly, to any of the **PARTIES** participating in the **TRIAL** for the purpose of gaining an improper advantage or unduly influencing the making of any decision. This includes payments or promises of payment, in kind and/or cash, as well as any other offerings of good or service.
  3. The **FOUNDATION** shall record in a reliable manner all economic transactions arising from this Agreement and shall make available to the SPONSOR, upon request in writing, the corresponding documentation that verify compliance with the commitments contained herein.

# TWELFTH. - JURISDICTION

* 1. In order to resolve any discrepancy in the application or interpretation of the provisions of this Agreement, the **PARTIES** submit, expressly waiving any jurisdiction that may correspond to them, to the jurisdiction of the courts and tribunals of the locality of the Community of Madrid where HOSPITAL is located.
  2. In the event that you have a copy of this Agreement in another language or language, the Spanish version shall prevail.

And for the conclusion, and in conformity, the **PARTIES** sign this document in triplicate and to a single effect.

By the **Cro/SPONSOR**,

Fdo.: Mr.

# FOR THE FOUNDATION,

The HOSPITAL,

Fdo.: Mrs. Emma Méndez Calleja Fdo.: Mr. César Adolfo Gómez Derch

Director Managing Director

# THE PRINCIPAL INVESTIGATOR

Fdo.: Dr.